Octagam® 10%: Octagam® 10% (IGIV) has been available through Canadian Blood Services since April 2013. Octagam® is manufactured by Octapharma. The Octagam® 5% formulation was first introduced in 1995, followed by the 10% formulation, which has been available worldwide since 2008. The introduction of Octagam® 10% provides to Canadian physicians and patients a generally well tolerated therapeutic IGIV option¹,². Octagam 5% is not currently available through the CBS. Please see Tolerability Profile section for further information.

Product Information²:
Formulation: Octagam® 10% is a sterile liquid preparation of highly purified immunoglobulin G (IgG) derived from large pools of human plasma.

Viral Inactivation/Removal: The viral safety of Octagam® 10% is ensured through effective manufacturing steps for virus inactivation/removal. Octagam® 10% is prepared by cold-ethanol fractionation of large pools of human plasma using two dedicated virus inactivation steps; a solvent detergent (S/D) method and a specific pH 4 treatment. The S/D method is regarded by the World Federation of Hemophilia as the “gold standard” in lipid enveloped virus inactivation³. However, as with all products prepared from human blood or plasma, the risk of transmission of infectious agents cannot be fully excluded. The pH 4 treatment also reduces anti-complementary activity and aggregation of the IgG polymers. The whole manufacturing process is carried out at a low pH in order to maintain the nativity of the IgG molecules.

Storage: Octagam® 10% can be stored at +2 °C to +8 °C for 23 months from the date of manufacture. Within this shelf-life the product may be stored up to 3 months at ≤ 25°C. After the storage at ≤ 25°C the product must be used or discarded.

Immunoglobulin content: Octagam® 10% contains not less than 96 mg/ml of IgG, the IgA content is ≤ 0.4 mg/mL.

Administration: Octagam® 10% is for intravenous administration only.

Plasma Source: The Octagam® 10% manufactured for Canada is made from pools of at least 3500 U.S. donor human plasma.

Half-Life: The pharmacokinetics of Octagam® 10% have not been formally studied in ITP, idiopathic thrombocytopenic purpura patients. Octagam® 5% has a mean half-life of about 40 days when measured in primary immunodeficiency (PID) patients, however the half-life may vary from patient to patient.

Indications: Octagam® 10% is indicated for Immune thrombocytopenic purpura (ITP) patients at high risk of bleeding or prior to surgery to correct the platelet count. Clinical data on pediatric patients (< 18 years old) is limited. Octagam® should be administered under the supervision of a qualified health professional who is experienced in the use of immunizing agents and in the management of immunodeficiency syndromes. Appropriate management of therapy and complications is only possible when adequate diagnostic and treatment facilities are readily available.

Octagam® 5% is indicated for replacement therapy in the following primary immunodeficiency syndromes: congenital agammaglobulinaemia and hypogammaglobulinaemia, common variable immunodeficiency, severe combined immunodeficiencies and secondary immunodeficiency syndromes: secondary hypogamma-globulinaemia in patients with chronic lymphocytic leukaemia (CLL), or multiple myeloma (MM) with recurrent infections and children with congenital AIDS who have bacterial infections.

Infusion Recommendations: Octagam® 10% should be intravenously administered initially at a rate of 1 mg/kg per minute (0.01mL/kg per minute) for the first 30 minutes. If well-tolerated, the rate may be gradually increased to a maximum of 12 mg/kg per minute (0.12 mL/kg per minute). If side effects occur, the rate may be reduced, or the infusion interrupted until symptoms subside. Please see the Product Monograph for complete dosing and administration recommendations.

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**Tolerability Profile:** In general, various minor allergic and hypersensitivity type of reactions and headache, chills, myalgia such as back or chest pain, fever, cutaneous reactions, and nausea may occasionally occur with Octagam® 10%. Reactions to intravenous immunoglobulins tend to be related to the dose and the rate of infusion.

**Vial Sizes:** In Canada Octagam® 10% is available in three vials sizes 5, 10 and 20 grams (50, 100 and 200mL glass bottles with integrated labels and hangers).

**Latex free:** Octagam® 10% is latex free.

**Contraindications:**

- Hypersensitivity to this drug or to any ingredient in the formulation or component of the container.
- History of an allergic reaction to any human immunoglobulin preparation or to any product constituent.
- Immunoglobulin A (IgA) deficiency, with known antibodies against IgA.

**Most serious warnings and precautions:**

**Thromboembolic events:** There is clinical evidence of an association between IGIV administration and thromboembolic events such as myocardial infarction, stroke, pulmonary embolism and deep vein thromboses. Caution should be exercised in prescribing and infusing IGIV in obese patients and in patients with pre-existing risk factors for thrombotic events (such as advanced age, hypertension, diabetes mellitus and a history of vascular disease or thrombotic episodes, patients with acquired or inherited thrombophilic disorders, patients with prolonged periods of immobilisation, severely hypovolemic patients, patients with diseases which increase blood viscosity).

**Viral transmission:** The physician should discuss the risks and benefits of this product with the patient before prescribing or administering to the patient.

**Other relevant warnings and precautions:**

- Cases of acute renal failure have been reported
- Aseptic meningitis syndrome has been reported
- Patients with corn allergies should avoid using Octagam® or be closely observed, because of the maltose content (disaccharide sugar, derived from corn)
- Transfusion-Related Acute Lung Injury has been rarely reported with IGIV products
- Obese, elderly patients should be treated with caution as overdose is possible in these patients
- Patients needing glucose testing should use glucose specific testing systems due to potential for falsely elevated glucose readings because of maltose content in Octagam®
- Interference with urine glucose testing due to maltose excretion via urine as maltose and glucose
- Use with caution in patients needing vaccination with live, attenuated vaccines, since IgG administration may impair the efficacy of these vaccines

**For more information:**

Please consult the Octagam® 10% Product Monograph at [http://www.octapharma.ca/fileadmin/user_upload/octapharma.ca/octagam_10_PM_20120222_853_PM_08_07 ENG.pdf](http://www.octapharma.ca/fileadmin/user_upload/octapharma.ca/octagam_10_PM_20120222_853_PM_08_07 ENG.pdf) for important information relating to adverse reactions, drug interactions and dosing information which have not been discussed in this piece. Consult the Octagam® 5% Product Monograph at [http://www.octapharma.ca/fileadmin/user_upload/octapharma.ca/Octagam5.pdf](http://www.octapharma.ca/fileadmin/user_upload/octapharma.ca/Octagam5.pdf) for contraindications, warnings, precautions, adverse reactions, interactions and dosing. The Product Monographs are also available by calling 1-888-438-0488.

**References:**